K140808

APR 17 2014

PHILIPS

5. 510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Penny Greco, Regulatory Affairs Specialist
Philips Healthcare, Ultrasound
3000 Minuteman Road
Andover, MA
Telephone: (978) 659-4615
Facsimile: (978) 975-7324
E-mail: penny.greco@philips.com

Date prepared: March 14, 2014

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Picture Archiving and Communications Systems Workstation

Proprietary Name: Q-Station

Classification Name: CFR 892.2050, system, image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that modifications introduced with Q-Station 3.0 are substantially equivalent to other commercially available devices including Philips Xcelera (K061995) and Philips EPIQ (K132304). The Q-Station analysis packages and multi-modality viewing are the same as those found on Philips ultrasound systems, including EPIQ.

4) Device Description

Q-Station is designed to manage post-acquisition ultrasound images and other data, for the purposes of diagnosing the patient's condition. This includes using Q-Station on a PC to review

images and measurements sent from an ultrasound acquisition device, analyze 3D and other data with QLAB. Q-Station is used to review various ultrasound exam types, including Adult echo, General Imaging, Stress echo, Vascular, and TEE. In addition, Q-Station can be used for reference viewing of non-ultrasound DICOM images. Q-Station can be used to add interpretive findings, key images, measurements and calculations and other comments that create reports that can be shared with other clinicians. During this review, users may also use Q-Station to import and export exams, print reports, and anonymize images for export. Q-Station supports QLAB Q-Apps for advanced analysis (K132165).

5) Intended Use

Q-Station is application software intended to manage, view, analyze, and report qualitative and quantitative image data from ultrasound exams. It is designed to host optional advanced analysis applications via QLAB integration and provides integrated tools that allow users to manually assess and score cardiac wall motion and export images and/or exams and reports. Q-Station can view DICOM images of non-ultrasound images such as CT, MR, NM, CR, MG, XA, PET, RT, and X-Ray modalities for reference viewing. It supports connectivity to ultrasound systems, PACS and other DICOM storage repositories.

6) Technological comparison to predicate devices

Philips Q-Station 3.0 is application software similar to Q-Station as submitted in K103815. It is designed to manage, view and report image data acquired by Ultrasound systems, but with Q-Station 3.0 now includes analysis packages and multi-modality viewing similar to Philips Xcelera and Philips EPIQ.

Both Q-Station and Xcelera are software applications for off-cart image analysis and patient report preparation. Both are DICOM compatible.

The integrated analysis packages included in Q-Station 3.0 are essentially the same as those included with the EPIQ ultrasound system (K132304), except that the Q-Station analysis packages are limited to Adult Echo, Pediatric Echo and Vascular applications. The Analysis packages are also similar to Philips Xcelera analysis packages (K061995).

The Q-Station 3.0 multi-modality viewing allows users to view non ultrasound images such as CT, MR, NM, CR, MG, XA, PET, RT, and X-Ray modalities for reference viewing. These images can be viewed in 1-up or in n-up for comparison. In cases where the images are present in stack format, Q-Station viewer will allow the user to navigate the frames/slices of these stacks and analyze them one by one. No modification is allowed on multi-modality images/studies, nor is reporting allowed on such studies. The Q-Station Multi-modality viewing is similar to that of both EPIQ and Xcelera.

Model	**Philips Q-Station**	**Philips Q-Station 3.0**	**Philips Xcelera**	**Philips EPIQ Ultrasound System**
510(k) Reference	K103815	Subject submission	K061995	K132304
Product Code	LLZ	LLZ	LLZ	IYN, IYO, ITX
Intended Use	Q-Station software is a software application package. It is designed to manage, view and report image data acquired by Ultrasound systems and cardiac waveformn data from Philips StressVue EGG systems. Q-Station offers support for QLAB plug-ins for analysis, quantification and reporting of data from ultrasound systems.	Q-Station is application software intended to manage, view, analyze, and report qualitative and quantitative image data from ultrasound exams. It is designed to host optional advanced analysis applications via QLAB integration and provides integrated tools that allow users to manually assess and score cardiac wall motion and export images and/or exams and reports. Q-Station can view DICOM images of non-ultrasound images such as CT, MR, NM, CR, MG, XA, PET, RT, and X-Ray modalities for reference viewing. It supports connectivity to ultrasound systems, PACS and other DICOM storage repositories.	An integrated multimodality image and information system, designed to perform the necessary functions required for import/export/storage/ archiving/review/ analysis/quantification/ reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.	The EPIQ Diagnostic Ultrasound System is a general purpose, software controlled diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in a various modes of operation.
Analysis Packages	No	Adult Echo Pediatric Echo Vascular	Xcelera packages include: Adult Echo Pediatric Echo Vascular	EPIQ packages include: Adult Echo Pediatric Echo Vascular
Measurement Tool	No	View, copy, and edit system-defined measurement labels, groups, and collections. Create, edit, and delete customized measurement labels, groups, and collections.	Create, edit, delete measurements & calculations and re-label existing measurements & calculations	Same as Q-Station 3.0
Viewer for other Modalities	No	CT, MR, NM, CR, MG, XA, PET, RT, and X-Ray images	Same + US	Same as Q-Station 3.0

7) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. Q-Station 3.0 was tested in accordance with Philips verification and validation processes. Quality assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validation

Summary of Clinical Tests:
The subject of this premarket submission, Q-Station 3.0 software did not require clinical studies to support substantial equivalence.

Conclusion:
Verification and Validation activities required to establish the performance, functionality, and reliability characteristics of Q-Station 3.0 were performed. Testing involved system level tests, performance tests, and safety testing from risk analysis. Testing performed demonstrated that the Q-Station 3.0 meets all defined reliability requirements and performance claims.

8) General Safety and Effectiveness Concerns
The device labeling contains operating instructions for the safe and effective use of the Q-Station 3.0 software.

9) Conclusions
The Q-Station software is designed and manufactured to meet United States and international standards for the display and reporting of qualitative and quantitative image data acquired on Phillips Ultrasound devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. The Q-Station software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
Buffalo, MN 55313

Re: K140808
Trade/Device Name: Q-station
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140808

Device Name

Q-Station

Indications for Use *(Describe)*

Q-Station is application software intended to manage, view, analyze, and report qualitative and quantitative image data from ultrasound exams. It is designed to host optional advanced analysis applications via QLAB integration and provides integrated tools that allow users to manually assess and score cardiac wall motion and export images and/or exams and reports. Q-Station can view DICOM images of non-ultrasound images such as CT, MR, NM, CR, MG, XA, PET, RT, and X-Ray modalities for reference viewing. It supports connectivity to ultrasound systems, PACS and other DICOM storage repositories.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*